Remarks

This Amendment is submitted in response to the office action mailed February 26, 2009, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on May 26, 2009. Submitted herewith is a Petition for a One-Month Extension of Time extending the due date to June 26, 2009 and a Request for Continued Examination Transmittal Form for the above-identified application. Accordingly, this Amendment is timely submitted.

Claims 26 through 51 are currently pending. Applicants respectfully request the entry of the amendments to Claim 43. Applicants respectfully submit that the amendments to this pending claim do not introduce any new matter.

Rejection under 35 U.S.C. § 112

Claim 42 was rejected under 3 U.S.C §112, first paragraph as failing to comply with the written description requirement. The Office Action asserts that the specification does not support the limitation that the particles have a glass temperature above 35°C. Applicants believe that the Office Action was intended to refer to Claim 43, which includes the referenced limitation that "the particles have a glass transition temperature above 35°C" and respond accordingly.

Applicants have amended Claim 43 to clarify that the excipient in the pharmaceutical liquid has a glass transition temperature above 35°C. Support for such an amendment can be found on page 14, lines 7-13 of the original specification.

In view of the foregoing arguments, Applicants respectfully submit that Claim 43 of the present application properly complies with the written description requirement of 35 U.S.C. §112, first paragraph. Applicants request that Claim 42 of the present application be reconsidered for allowance and the Examiner's rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b) and § 103(a)

Claims 26, 27, 29-34, 36-41, 44-46 and 48-51 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Platz et al., U.S. Patent No. 6,051,256 (hereinafter "Platz"). The Examiner has asserted that Platz shows a spray drying system for forming a pharmaceutical formulation comprising "an atomizer (57), the atomizer comprising a first, annular channel (100) through which a pharmaceutical liquid flows, the channel comprising a constriction (104) for spreading the pharmaceutical liquid into a thin film in the channel, the atomizer further comprising a second channel (102) through which an atomizing gas flows, the second channel being positioned so that the atomizing gas impinges the liquid thin film to produce droplets, a drying chamber (50) to dry the droplets to form particles; and a collector (76) to collect the particles." Further, Platz has

been cited for teaching the constriction sizes, the third channel for gas flow, the specific inlet and outlet temperatures, the particles having a rugosity above 2, and/or a diameter of less than 20 micrometers. The Examiner has therefore concluded that Platz meets the limitations of the present invention as claimed.

Although Platz teaches a method for preparing ultrafine powders of biological macromolecules by atomizing liquid solutions of macromolecules, nowhere does Platz disclose the use of an atomizer having (1) a first channel comprising a constriction for spreading the pharmaceutical liquid into a thin film, (2) any preparation of a liquid thin film, or (3) a separate second channel through which atomized gas flows and positioned so that the atomizing gas impinges the liquid thin film to produce droplets. Platz describes a spray drying apparatus having an inner conduit (for carrying the solution) and an outer conduit (for carrying the atomizing gas), wherein the outer conduit must be "disposed coaxially about the inner conduit". (Col. 14, lines 2-4.) Solely disclosing that the inner conduit "terminates in an orifice" (Column 13, lines66-67), Platz does not teach or suggest that the inner conduit includes any "constriction for spreading the thin pharmaceutical liquid into a thin film" as required by present invention. Platz further does not teach or suggest any second channel "positioned so that the atomizing gas impinges the liquid thin film" to produce droplets. Since Platz does not teach or suggest any apparatus having a first channel comprising a constriction for spreading the pharmaceutical liquid into a thin film and/or any separate second channel positioned so that the atomizing gas impinges this liquid thin film to produce droplets, the presently claimed invention is distinguishable from Platz.

Applicants respectfully submit that Claims 27, 29-32, 34, 36-41, 44, 46 and 48-51 are in condition for allowance as they depend from an allowable independent claim. In addition, Platz does not teach or suggest any apparatus having a third channel for gas flow as mentioned in the Office Action.

Thus, in view of the foregoing arguments, Applicants respectfully request withdrawal of the rejection of Claims 26, 27, 29-34, 36-41, 44-46 and 48-51 are rejected under 35 U.S.C. §102(b).

Claims 28, 35, 42, 43 and 47 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Platz. Relying upon the same arguments above in combination with the case *Garner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), the Examiner states that dependent claims 28, 35 and 47 are obvious since it would have been obvious to one of ordinary skill in the art to make the constriction diameter less than 0.005 in order to increase the velocity and turbulence of the fluid as it passes through the restriction point. The Examiner further states that dependent claims 42 and 43 are obvious since "it has been held to be within the general skill of a worker in the art to select a know [sic] material on the basis of its suitability for the intended use of the device".

Graham v. John Deere Co. of Kansas City, 383 U. S. 1, 17–18 (1966), establishes an objective analysis for applying §103 to a question of obviousness: "the scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . ascertained; and the level of ordinary skill in the pertinent art resolved." The USPTO bears the burden of establishing a *prima facie* case of obviousness based on the results of the factual inquiries under *Graham*. The *prima facie* case generally requires three showings: 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; 2) a reasonable expectation of success; and 3) that the prior art reference or combination of references teaches or suggests all the claim limitations. M.P.E.P. §2143.

The Applicants respectfully submit that a *prima facie* case of obviousness has not been established. A *prima facie* case of obviousness must establish that the prior art reference or combination of references teach or suggest all the claimed limitations. M.P.E.P. § 2143. Contrary to the Examiner's assertion, one of ordinary skill's knowledge of relative dimensions and material selection is not sufficient to render the present invention obvious in view of Platz. As explained above for independent claims 26, 33 and 45, Platz alone does teach or suggest any apparatus having a first channel comprising a constriction for spreading the pharmaceutical liquid into a thin film and/or any separate second channel positioned so that the atomizing gas impinges this liquid thin film to produce droplets as required by the present invention. These deficiencies are not cured by the asserted knowledge of one of ordinary skill.

On page 8, lines 21-30 and Figure 5 of the original specification, Applicants expressly provided a detailed explanation of the differences between the technical features and advantages of the present invention and the atomizer of Platz (U.S. Patent No. 6,051,256). Applicants expressly stated:

> The atomizer 40 according to the invention provides significantly improved atomization efficiency and allows for the ability to create smaller and more uniform liquid droplet sizes. For example, droplets less than 35 microns, and preferably less than 10 microns may be generated. The advantage of smaller droplet sizes is that a smaller final particle size for a given solid concentration may be obtained. Alternatively, a solid concentration may be increased while maintaining a particular particle size. This would allow for increased system throughput. The increased size distribution is shown in FIG. 5. FIG. 5 shows a graph of droplet diameter as a function of radial distance from the centerline of the atomizer for both the atomizer 40 of FIG. 4 and a prior art atomizer of U.S. Pat. No. 6,051,256. As can be seen, the

droplet diameter is significantly more uniform and smaller for the atomizer 40 of the present invention.

(Page 8, lines 21-30 of the original specification.) . By incorporating a first channel comprising a constriction for spreading the pharmaceutical liquid into a thin film and any separate second channel positioned so that the atomizing gas impinges this liquid thin film to produce droplets, the present invention can provide significantly smaller and more uniform liquid droplet sizes than Platz. The technical data provided on page 8, lines 21-30 and Figure 5 of the original specification demonstrate the advantages and significance of the improved technical features of the present invention over Platz.

Thus, in view of the foregoing arguments, Applicants respectfully request withdrawal of the rejection of Claims 28, 35, 42, 43 and 47 under 35 U.S.C. § 103(a).

In view of the foregoing arguments, Applicants respectfully request that the claims of the present application be reconsidered for allowance. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone her at the telephone number provided below.

Respectfully submitted,

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